MISSOURI BOARD OF PHARMACY

NEWSLETTER

FEBRUARY 2024

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INTRODUCING THE MISSOURI PHARMACY WELL-BEING PROGRAM

The Board is pleased to announce that the Missouri Pharmacy Well-Being Program is now open and accepting participants!

What is The Pharmacy Well-Being Program?

The Missouri Pharmacy Well-Being Program (WBP)* is a confidential resource for Missouri licensed/registered pharmacists, intern pharmacists, and pharmacy technicians who have life problems, including substance disorders, mental health stress, and other issues which prevent them from functioning at full capacity.

The Board has contracted with the Missouri Association of Osteopathic Physicians & Surgeons (MAOPS) to administer the Pharmacy WBP, as part of the MAOPS Physician & Health Professional Wellness Program. Program administrators have extensive experience in addictionology, mental health, & healthcare professional wellness.

PHARMACY WBP GOALS

To protect the public by:

- Ensuring safe and competent pharmacy practice
- Facilitating safe return to health and personal and professional functioning

How Does The Program Work?

"Health professionals, like anyone else, are susceptible to substance, psychiatric and medical illnesses. If left untreated, these illnesses can put even the finest clinicians and their patients at risk. Many do not get the help they need due to the social stigma, fear of exposure, or lack of awareness." MAOPS Physician & Health Professional Wellness Program.

The Missouri Pharmacy WBP can assist Board licensees/registrants with locating counseling and treatment resources for life problems that may prevent them functioning at full capacity, including:

- Addiction/ Impairment
- Mental health
- Substance abuse disorders
- Cognitive impairments
- Medical conditions
- Disruptiveness
- Burnout

Licensees/registrants can also voluntarily enroll in the Pharmacy Well-Being Program for professional evaluation and monitoring through the WBP; Board approval is not required.

Once enrolled, Pharmacy WBP administrators will provide treatment resources and coordinate care for the health professional throughout the individual's participation in the Program:

- Evaluation and treatment by an approved provider begins immediately following enrollment in most cases. Treatment typically takes place at a facility outside of the health professional's normal environment.
- Voluntary Participants will sign a contract with the Pharmacy WBP that outline treatment requirements and support opportunities based on professional recommendations. Individuals will be directed to better-suited resources if the Pharmacy WBP is not necessary.
- The Pharmacy WBP will provide ongoing professional support and monitoring during the treatment process to assist Participants with reaching and maintaining their optimal health status.

Is This Discipline?

No! Voluntary participation in the Pharmacy WBP is not disciplinary action and the Pharmacy Well- Being/MAOPS Wellness Program is not a licensing or disciplinary authority. Instead, the Pharmacy WBP provides a non-disciplinary option for protecting the public through early identification, intervention, and treatment.

Confidentiality?

By statute, the identity of all self-referred voluntary participants is confidential. It will not be disclosed to the Missouri Board of Pharmacy, except as otherwise provided by § 338.380.6 of the Revised Statutes of Missouri. Confidentiality and anonymity of program participants and referral sources will be kept confidential, as authorized by law.

Fees/Costs

Voluntary Participants are responsible for program costs; Insurance coordination questions can be discussed with WBP administrators.

Contact

If you or someone you know needs help, contact the Pharmacy Well-Being Program at: (573) 632-5562 or contact:

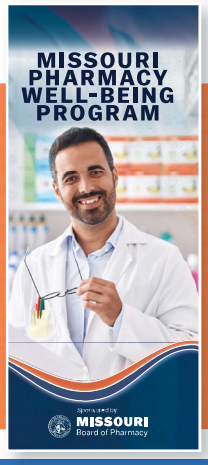
Heather Johns, LCSW, Director
hjohns1@crmc.org

Lori Rosburg, Ed.S Mental Health Counseling
PHP Program Coordinator
Lori.Rosburg@crmc.org

William "Russ" Carpenter, DO
Medical Director
wcarpenter@crmc.org

See additional information online.

Download a copy of the Pharmacy WBP Brochure.



ADMINISTERING RSV VACCINE BY MEDICAL PRESCRIPTION ORDER

Since statute 338.010 does not allow a pharmacist to order/administer or use a physician protocol to administer the Respiratory Syncytial Virus (RSV) vaccine, many pharmacists are obtaining a prescription from the patient's healthcare provider to administer the vaccine. Regulation 20 CSR 2220-6.040 Administration by Medical Prescription Order covers this activity.

Some regulation highlights:

- Pharmacists must have a current and accurate written policy and procedure manual that covers all aspects of administering medication by prescription order.
- Pharmacists are required to submit a Notification of Intent (NOI) to administer by medical prescription order. This is a separate NOI submission than the NOI for administering vaccines by pharmacist authority or protocol. A pharmacist may check to see if they have submitted the appropriate NOI(s) by conducting a licensee search on the Board's website. The search will list the current NOI(s) on file:

Certification Type:	Effective Date:	Expiration Date:
NOI - Administration by Protocol	8/5/2022	10/31/2024
NOI - Administration by Medical Prescription Order	8/5/2022	10/31/2024

Pharmacists may submit a NOI here. If needed, pharmacists can request their PIN here.

- RSV vaccines must be administered in accordance with treatment guidelines established by the Centers for Disease Control and Prevention (CDC) or in accordance with manufacturer's guidelines.
- The vaccine prescription is not required to have the "Pharmacist to Administer" statement.

Pharmacists should review the entire regulation to ensure compliance.

Currently, there are two RSV vaccines on the market, Abrysvo and Arexvy. If a prescription is issued for a specific RSV vaccine brand, prescriber contact and documented authorization are required to make a substitution to the other brand.

E-ALERTS

Sign up on the Board's website to receive e-alerts on Board news, compliance updates and licensing changes.

RECENT REVISIONS TO THE COMPOUNDING REGULATION

Regulation 20 CSR 2220-2.400 Compounding Standards of Practice was revised effective 9/30/2023. Revisions included additional requirements for bulk drug substances used in compounding and further clarification on the compounding of a preparation that is a copy or essentially a copy of a commercially available product.

The following sections were revised:

(6)

(B) Pharmacists shall only receive, store, or use drug substances for compounding that have been made and/or distributed by Missouri licensed/registered drug distributors. A bulk drug substance for human use that is not the subject of an applicable United States Pharmacopeia or National Formulary monograph or is not a component of a Federal Drug Administration (FDA) approved drug cannot be used in compounding unless it appears on a list promulgated as a regulation pursuant to section 503A(b)(1)(A)(i)(III) of the Federal Food, Drug, and Cosmetic Act, except as otherwise allowed by the FDA.

(9) The compounding of a preparation that is a copy or essentially a copy of a commercially available product is prohibited except when there is a specific medical need for a particular variation of a commercially available compound for an individual patient as determined by the prescriber, or when a change or modification for a specific patient would produce for that patient a clinically significant difference between the compounded preparation and the comparable commercially available drug product, as determined by the prescribing practitioner. Documentation from the prescriber of the specific medical need or clinically significant difference for a specific patient must be maintained in the pharmacy's records. A prescription that identifies only a patient name and compounded preparation formulation is insufficient documentation for a pharmacy to rely upon to conclude that the prescriber made a determination regarding a specific medical need or clinically significant difference. A different formulation without a documented specific medical need or clinically significant difference is not sufficient.

(A) For purposes of this rule, "essentially a copy of commercially available product" is a compounded preparation that has—

1. The same active pharmaceutical ingredient(s) as the commercially available drug product;
2. The same, similar, or an easily substitutable dosage strength; and
3. The same manner of administration as the commercially available drug product.

(B) For purposes of this rule, "easily substitutable" means the same or similar dosage strength can be achieved by administration of fractional or multiple doses of a commercially available drug product.

(C) When compounding an otherwise commercially available product due to a drug shortage, the pharmacy must confirm and document the commercially available product is not available despite due diligence.

Pharmacists should review the entire regulation to ensure compliance.

REPORTS OF FRAUDULENT E-PRESCRIBED PRESCRIPTIONS

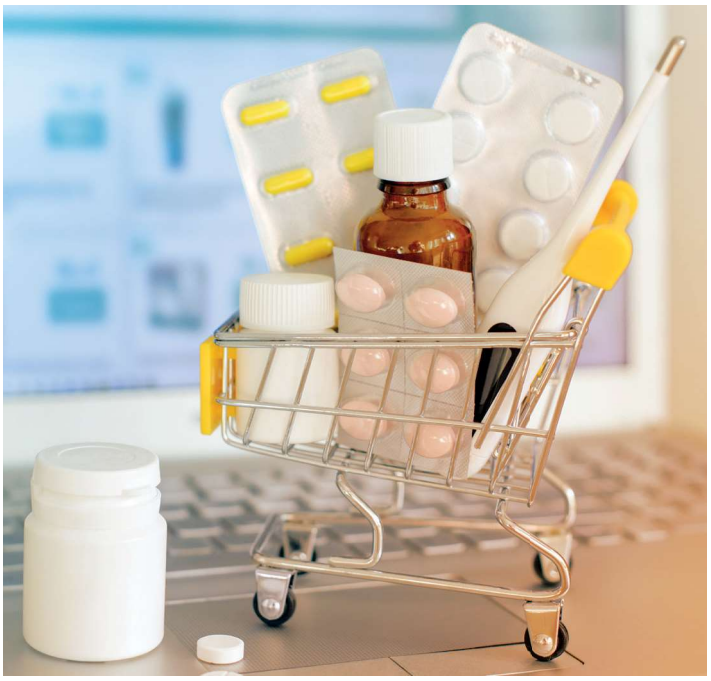
The Board continues to receive reports of pharmacies receiving fraudulent e-prescribed controlled substance prescriptions. The pharmacies received the prescriptions via their normal e-prescription delivery system. Reports have included prescriptions for Promethazine with Codeine and Oxycodone, in combination with an antibiotic or a NSAID, with the prescribers being both in and out-of-state. Pharmacists are encouraged to call the prescriber on any suspicious e-prescriptions. If found to be fraudulent, an online report may be filed with the DEA here.

SECURITY TIPS

Law enforcement has reported a number of nationwide pharmacy break-ins where criminals may have obtained critical pharmacy security information from social media posts. Examples include online posts showing the C-II cabinet, location of security cameras, storage shelves behind the pharmacy counter, and internal exit/security doors. In some cases, pharmacy staff posted selfies on their personal accounts with key pharmacy images in the background that thieves may have been able to use to gain access.

Social media is a great way for pharmacies to connect with the public. Make sure information isn't posted that could place the pharmacy at risk. Talk with pharmacy staff about what is allowed. Security is everyone's responsibility!

See RxPatrol for additional pharmacy security tips and resources, including, a Pharmacy Security Checklist. (RxPatrol is a collaborative effort between law enforcement and industry. This site is provided for informational purposes only and is not sponsored by the Board).



GOLD CERTIFICATES

MISSOURI BOARD OF PHARMACY

50 years Congratulations!

Congratulations to our newest "gold certificate" pharmacists who have maintained a Missouri pharmacist license for 50 years:

David L Carmichael
Larry A Otto
Patricia M Mitchell
Fred M Tichy
Roy L Wheeler
Dennis C Engquist
Steven C Hutcheson
Richard L Seibert
Robert A Shaw

RECENT DISCIPLINARY ACTIONS

INTERNS:

Conley, Alex T. #2021038146, Corpus Christi, TX. Intern Pharmacist license revoked; license disciplined in Kansas and entered into a nolo contendere plea and was convicted of domestic violence and unlawfully and intentionally damaging property. Section 338.055.2 (2), (3), (5), (6), (8), (13), (15), and (17) RSMo.

Mense, Mary-Margaret, #2015031894, Liberty, MO. Revoked, and cannot reapply for seven (7) years. Intern admitted to diverting controlled substances, including Hydrocodone/acetaminophen, Oxycodone, and Oxycodone/acetaminophen. Section 338.055.2(5), (13), (15) and (17) RSMo.

Moylan, Madison, #2022001106, St. Louis, MO. Probation for three (3) years. Intern terminated from Pharmacy for failed employment drug test, did not have a valid prescription for substance for which she tested positive. Section 338.055.2(5), (13), (15), and (17), RSMo.

PHARMACIST:

Bechtel, Randy, #042177, Monett, MO. Public Censure. As a pharmacist, created fraudulent prescriptions and filling them. Section 338.055.2 (5), (6), (13) and (15), RSMo.

Crosetti, Sean, #2015000846, Grain Valley, MO. Three (3) years probation. As PIC, multiple inspection violations, multiple compounding violations, unsanitary conditions, administered vaccines under pharmacist name, unsecured pharmacy area, C-II not stored in a locked area. Section 338.055.2(5), (6), (12), (13) and (15) RSMo.

Eursiriwan, Robert P., #2021032275, St. Louis, MO. Five (5) years probation. As pharmacist, diverted Alprazolam for personal use and consumption from the pharmacy without a valid prescription. Section. Section 338.055.2 (5), (6), (13), (15) and (17), RSMo.

Jancich, Mary, #044855, Basehor, KS. License revoked. Pharmacist's license disciplined in Kansas. Section 338.055.2 (5), (8), and (13) RSMo.

Spalitto, Peter A., #042082, Sunrise Beach, MO. Three (3) years probation. As pharmacist-in-charge, the pharmacy dispensed multiple controlled substance prescriptions from prescribers prior to verifying the prescriber held a current and active DEA registration. Pharmacy dispensed controlled substance prescriptions under expired prescriber DEA registrations, non-physician DEA registrations, and wrong DEA registrations. Section 338.055.2 (6) and (15) RSMo.

Sullivan, Melissa N., #045144, Shawnee, KS – Five (5) years probation. As pharmacist, was impaired while working in the pharmacy. Admits to improper alcohol use/alcohol abuse. Pleaded guilty to a class B misdemeanor in the Circuit Court of Platte County (Suspended imposition of sentence). Section 338.055.2(1), (5), and (13), RSMo.

PHARMACIES:

Crosetti Health and Wellness d/b/a Crosetti's, #2020038375, Grain Valley, MO. Three (3) years probation. Multiple inspection violations, multiple compounding violations, unsanitary conditions, unsecured pharmacy area, C-II not stored in a locked area. Section 338.055.2(5), (6), (12), (13) and (15) RSMo.

Easy Rx Pad LLC, d\b\a Procure Pharmaceutical Services, #2023040381, Burgettstown, PA. Probation ending May 19, 2026. Previous permit under probation until May 19, 2026, for dispensing controlled substances initiated by nurses at Missouri hospice facilities. The faxed medication orders did not contain the prescriber's signature or documentation that the prescription had been verbally verified.

HDM Pharmacy, #2005004510, Lexington, KY. Two (2) years probation. Disciplinary action in KY for failing to compound sterile preparations pursuant to USP Chapter 797. Disciplinary action in AL for conducting business without a current or valid permit. Shipping sterile prescriptions into Missouri without a Class H and for not following Missouri sterile compounding rules. Section 338.055.2 (6) and (8), RSMo.

Healthdirect Institutional Pharmacy Services Inc., Farmington, MO. Three (3) years probation. Routine inspection revealed multiple violations including sterile compounding violations. 338.055.2 (5), (6), (13), and (15) RSMo.

PHARMACIES (CONT.)

Spalitto's Pharmacy, #006292, Kansas City, MO. Three (3) years probation. The pharmacy dispensed multiple controlled substance prescriptions from prescribers prior to verifying the prescriber held a current and active DEA registration. Pharmacy dispensed controlled substance prescriptions under expired prescriber DEA registrations, non-physician DEA registrations, and wrong DEA registrations. Section 338.055.2 (6) and (15) RSMo.

Walgreens #04530, #006606, Kansas City, MO. Three (3) years probation. Multiple inspection violations: unsanitary conditions in the pharmacy, outdated drug products in active inventory, failed to post pictures on license, unlabeled vials in active inventory. 338.055.2 (6), (12), (13), and (15) RSMo.

Walgreen #06432, 004865, Brentwood, MO. Public Censure. Pharmacy had multiple controlled substance losses, failure to implement effective security controls. Section 338.055.2 (6), (13), and (15), RSMo.

Walgreen #06472, 004758, St. Louis, MO. Public Censure. Pharmacy had multiple controlled substance losses, failure to implement effective security controls. Section 338.055.2 (6), (13), and (15), RSMo.

NATIONAL ASSOCIATION OF BOARDS OF PHARMACY® NATIONAL PHARMACY COMPLIANCE NEWS – FIRST QUARTER 2024

(The following information was provided by the National Association of Boards of Pharmacy and is reprinted with permission of NABP. This information is provided for informational purposes only and does not express or represent the views or opinions of the Missouri Board of Pharmacy.)

NABP PRESIDENT NEWSOME HIGHLIGHTS MENTAL HEALTH CONCERNS IN ADDRESS TO THE PHARMACY COMMUNITY

NABP has released a video from NABP President Lenora S. Newsome, PD, in which she discusses her presidential initiative addressing the critical issue of mental health and well-being in the practice of pharmacy. In the heartfelt video message, Dr Newsome, a devoted southern Arkansas pharmacist with 43 years of experience, expresses her deep concern for the mental health of pharmacists, pharmacy technicians, and patients. In her address, she sheds light on the pressing challenges pharmacists face, particularly since the onset of the COVID-19 pandemic, which led to burnout and a shortage of pharmacy professionals. She also highlights the importance of pharmacists' mental health due to the impact they can have on patients' lives, recalling a moment when a simple conversation helped prevent a potential suicide of a patient. NABP President Newsome's video message is available on NABP's YouTube page.

FDA WARNS PHARMACIES TO INSPECT OZEMPIC PRODUCT INFORMATION FOR SIGNS OF COUNTERFEITS

Food and Drug Administration (FDA) is warning retail pharmacies, health care professionals, wholesalers, and patients to check their Ozempic® (semaglutide) products' lot and serial numbers to avoid purchasing counterfeit versions. Products with the lot number NAR0074 and serial number 430834149057 should not be used or distributed. FDA testing revealed that the needles in the sampled products are counterfeit and present an increased risk of infection for patients, as their sterility cannot be confirmed. Furthermore, other counterfeit parts of the sampled product include the pen label, health care professional and patient information, and carton. To date, the administration is aware of five adverse reactions from this specific illicit product, and they are common side effects associated with authentic Ozempic, which are nausea, abdominal pain, vomiting, constipation, and diarrhea. Retail pharmacies are advised to purchase genuine Ozempic from Novo Nordisk's list of authorized distributors and to check the legitimacy of their shipments by reviewing the photographs and information on the products. For reference, images of authentic and illegitimate versions of Ozempic are available on FDA's website.

HHS PUBLISHES RESOURCES FOR HEALTH CARE PROVIDERS ABOUT PROTECTING PATIENTS' HEALTH INFORMATION WHEN USING TELEHEALTH

The United States Department of Health and Human Services (HHS) has published two resources aimed at educating health care providers and patients about the privacy and security risks to their protected health information when using telehealth services. Health care providers are not required by the Health Insurance Portability and Accountability Act to educate patients on using telehealth services; however, these resources help support the use of telehealth services in order to expand patients' access to health care. The Educating Patients about Privacy and Security Risks to Protected Health Information when Using Remote Communication Technologies for Telehealth document guides health care workers on explaining the various types of telehealth services, the ways patients can decrease accidental disclosures of health information, and where they can file a privacy complaint if their privacy rights have been violated. The Telehealth Privacy and Security Tips for Patients document offers additional recommendations on how patients can protect their health information, such as by ensuring all available security updates are installed on electronic devices and removing health information from electronic devices when it's no longer needed. More information about monitoring privacy and security when receiving telehealth care can be found on the HHS website.

ASOP GLOBAL RELEASES SURVEY NOTING CONSUMERS ARE INCREASINGLY PURCHASING MEDICATIONS THROUGH ONLINE PHARMACIES

The Alliance for Safe Online Pharmacies (ASOP Global) has released a survey that shows Americans are increasingly purchasing medications through online pharmacies. Based on the perceptions of 1,500 American consumers, 69% of Americans said they felt comfortable being prescribed a controlled substance (CS) by a health care professional who they met only through telehealth appointments. However, the survey also found that 47% of consumers said they believe the top search results are safe and from verified pharmacies. A significant portion of Americans are motivated by cost savings and convenience to buy from online pharmacies. The survey cited that 55% of Americans said they would be open to purchasing from online pharmacies that are not approved by the United States government if they saved them money or if the medication was unavailable at their local pharmacy. ASOP Global is advocating for the implementation of comprehensive regulation that protects consumers from purchasing fake or substandard medication online and for Drug Enforcement Administration to not place high restrictions on telehealth prescribing of CS. This study is available on ASOP Global's website.

NASCSA OFFERS FREE CE CREDIT ACTIVITY EXPLAINING THE IMPACT OF PHARMACY-REPORTED PMP DATA

The National Association of State Controlled Substances Authorities (NASCSA) has partnered with Talem Health to create a one-hour, on-demand continuing education (CE) activity for pharmacists and pharmacy technicians to improve prescription monitoring program (PMP) data. The Data Quality in Prescription Monitoring Programs course will provide insight into how pharmacy staff data entry processes affect PMP data, clinical decision making, and downstream data analysis. Developed in partnership with NASCSA and 12 PMP administrators, the program analyzes the importance and value of complete, accurate data reported by dispensers to PMPs and assesses the impact of intentional or unintentional data entry errors and omissions on patient safety. It also discusses the downstream impacts of pharmacy-reported PMP data on clinical decision-making processes and helps pharmacy staff identify and implement changes that can be made in their practice setting to improve PMP data integrity. The CE activity is available until October 20, 2024, and is available on the TalemHealth website.

ISMP SAFETY BRIEF: UNINTENTIONAL INGESTION OF BORIC ACID VAGINAL SUPPOSITORIES

This column was prepared by the Institute for Safe Medication Practices (ISMP), an ECRI affiliate.

A doctor told a woman with a vaginal infection to use boric acid suppositories to help relieve symptoms that often accompany vaginitis, such as a bad odor. Boric acid (a pesticide that is harmful when taken orally) suppositories are sold over-the-counter and do not require a prescription. What is confusing is that boric acid suppositories come as a powder inside a gelatin capsule that looks similar to oral capsules. Also, they are often packaged in plastic bottles as loose capsules that resemble oral medications or dietary supplement products. In fact, people who have had an infection in the past may have been prescribed medication in a capsule, such as an oral antibiotic, to treat the infection. Patients may not be familiar with capsules used as suppositories.

In the report the Institute for Safe Medication Practices (ISMP) received, the patient swallowed one of the suppositories. Later, when she read the container label more carefully, she realized the capsules were suppositories meant for vaginal insertion. There was also a warning on the container that said, "For vaginal use only, not for oral consumption. If swallowed, get medical help and call poison control right away." The woman decided to go to an emergency room. According to poison control (https://www.poison.org/articles/does-boric-acid-treat-vaginal-yeast-infections), the small amount of boric acid in a single capsule would not be expected to cause harm. However, ingesting large amounts of boric acid may result in gastrointestinal distress, kidney problems, or death. Fortunately, the patient did not suffer any serious problems. A search of the internet revealed numerous other cases of women swallowing boric acid suppositories unintentionally.

Given that the basic problem is patients confusing boric acid suppositories for oral capsules, ISMP is asking Food and Drug Administration and product manufacturers to investigate ways this common error can be prevented. For example, consider reformulating products so they are shaped as suppositories. Most suppositories are waxy and small, with a round or cone shape; vaginal suppositories are usually oval and are not gelatin capsules filled with powder. These products should also be sold in unit-of-use blister packs, with the carton holding enough for use over a typical course of treatment, which is seven to 14 days. Vaginal products should also include an applicator with instructions and a link to a professional video that explains what a vaginal suppository is and how to properly use them. Additionally, the cartons and individual blisters need to call out the name of the product (boric acid) and a more conspicuous warning, such as "For vaginal insertion only." Community pharmacies may consider moving these products closer to the pharmacy counter to better enable pharmacists to support and educate patients on the safe use of these products.